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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,651	10/08/2003	Lawrence A. Shimp	2004367-0029	7263

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CHOATE, HALL & STEWART LLP
TWO INTERNATIONAL PLACE
BOSTON, MA 02110

EXAMINER

HAGOPIAN, CASEY SHEA

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 11/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/681,651

Applicant(s)

SHIMP ET AL.

Examiner

Casey Hagopian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-84 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Receipt is acknowledged of applicant's Oath and Power of Attorney filed 9/22/2004 and Information Disclosure Statement filed 9/7/2004.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-12, 16-24 and 27-29, drawn to a method of making a bone-polymer composite comprising a) bone particles, b) treating bone particles with coupling agent, and c) incorporating the treated bone particles into a polymer, classified in class 523, subclass 113.
 - II. Claims 6 and 13-15, drawn to the method of making a bone-polymer comprising steps to chemically modify a silane coupling agent, classified in class 523, subclass 113.
 - III. Claims 25-26, drawn to the method of making a bone-polymer composite comprising steps to modify the composite surface, classified in class 523, subclass 113.
 - IV. Claims 30-33, drawn to the method of making an osteoimplant, classified in class 623, subclasses 16.11, 23.58, 23.61 and 23.63.
 - V. Claims 34-44, 48-53 and 56-58, drawn to a composite comprising bone particles and a polymer, wherein the bone particles and polymer are covalently linked thru a silane coupling agent, classified in class 523, subclass 113.

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- VI. Claims 45-47, drawn to a composite wherein the silane coupling agent is chemically modified, classified in class 523, subclass 113.
- VII. Claims 54-55, drawn to a composite wherein the surface of the composite is modified, classified in class 523, subclass 113.
- VIII. Claims 59-69, 73-78 and 81-83, drawn to an osteoimplant, classified in class 623, subclasses 16.11, 23.58, 23.61 and 23.63.
- IX. Claims 70-72, drawn to an osteoimplant wherein the silane is chemically modified, classified in class 623, subclasses 16.11, 23.58, 23.61 and 23.63.
- X. Claims 79-80, drawn to an osteoimplant wherein the surface of the composite is modified, classified in class 623, subclasses 16.11, 23.58, 23.61 and 23.63.
- XI. Claims 84, drawn to a method of modifying a surface of a construct, classified in class 523, subclass 113.

3. The inventions are distinct, each from the other because:

4. Inventions I-III and V-VII, inventions IV and VIII-X and invention XI are unrelated.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, function and effects. Each set of inventions are unrelated because inventions I-III and V-VII are drawn to a bone-polymer composite and methods of making thereof, inventions IV and VIII-X are drawn to an osteoimplant

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and methods of making thereof, and invention XI is drawn to a method of modifying a surface of a construct. Thus, inventions I-III and V-VII, inventions IV and VIII-X and invention XI have different issues regarding patentability and enablement. Art anticipating inventions I-III and V-VII would not anticipate or render obvious inventions IV and VIII-X or invention XI and art anticipating inventions IV and VIII-X would not anticipate or render obvious invention XI. The different inventions require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden.

5. Inventions I-III and inventions V-VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the processes as claimed can be used to make materially different products and the products as claimed can be made by materially different processes. Inventions I-III are drawn to a method of making a bone-polymer composite and inventions V-VII are drawn to a composite comprising, in particular, a silane coupling agent and as such they have different issues regarding patentability and enablement. Art anticipating inventions I-III would not anticipate or render obvious inventions V-VII. The different inventions require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden.

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6. Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, functions, and effects. Invention I is drawn to a method of making a bone-polymer composite; invention II is drawn to a method of making a bone-polymer composite comprising a silane coupling agent; and invention III is drawn to a method of making a bone-polymer composite comprising further modifying the composite surface. The methods differ in scope because they comprise different method steps and as such the inventions I-III have different issues regarding patentability and enablement. Art anticipating any group I-III would not anticipate or render obvious the remaining groups I, II, or III. The different methods require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden.

7. Inventions V-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, functions, and effects. Invention V is drawn to a composite; invention VI is drawn to a composite comprising a chemically modified silane coupling agent; and invention VII is drawn to a composite wherein the composite surface has been modified. The inventions V-VII differ in scope because they comprise different elements that are not included in all of

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the inventions V-VII, and as such the inventions V-VII have different issues regarding patentability and enablement. Art anticipating any group V-VII would not anticipate or render obvious the remaining groups V, VI, or VII. The different products require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden.

8. Inventions IV and inventions VIII-X are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make materially different products. Inventions IV is drawn to a method of making an osteoimplant and inventions VIII-X are drawn to an osteoimplant wherein the polymer cannot be a polyaromtic polymer, and as such invention IV and inventions VIII-X have different issues regarding patentability and enablement. Art anticipating invention IV would not anticipate or render obvious inventions VIII-X. The different inventions require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden.

9. Inventions VIII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

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the instant case the different inventions have different modes of operation, functions, and effects. Invention VIII is drawn to an osteoimplant; invention IX is drawn to an osteoimplant comprising a chemically modified silane coupling agent; and invention X is drawn to an osteoimplant wherein the composite surface has been modified. The inventions VIII-X differ in scope because they comprise different elements that are not included in all of the inventions VIII-X, and as such the inventions VIII-X have different issues regarding patentability and enablement. Art anticipating any group VIII-X would not anticipate or render obvious the remaining groups VIII, IX, or X. The different products require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden.

10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

11. Because these inventions are distinct for the reasons given above and the search required for each Group I-XI is not required for every Group I-XI, restriction for examination purposes as indicated is proper.

12. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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13. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

15. Due to the complexity of the action, examiner submitted the Election Restriction in writing in lieu of calling applicant's attorney.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on M-F from 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

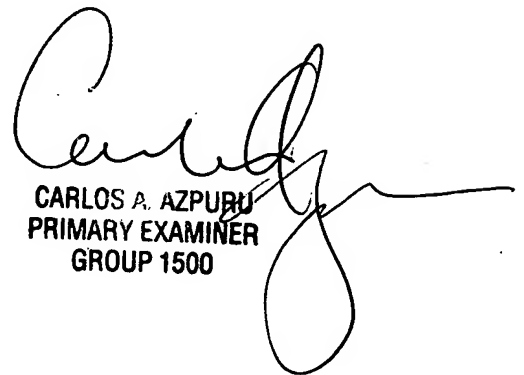
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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Casey Hagopian
Examiner
Art Unit 1615



CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500